

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

UNITED STATES OF AMERICA,
THE STATE OF CALIFORNIA,
THE STATE OF DELAWARE,
THE DISTRICT OF COLUMBIA,
THE STATE OF FLORIDA,
THE STATE OF GEORGIA,
THE STATE OF HAWAII,
THE STATE OF ILLINOIS,
THE STATE OF INDIANA,
THE STATE OF LOUISIANA,
THE COMMONWEALTH OF MASSACHUSETTS,
THE STATE OF MONTANA,
THE STATE OF NEVADA,
THE STATE OF NEW HAMPSHIRE,
THE STATE OF NEW JERSEY,
THE STATE OF NEW MEXICO,
THE STATE OF NEW YORK,
THE STATE OF OKLAHOMA,
THE STATE OF RHODE ISLAND,
THE STATE OF TENNESSEE,
THE COMMONWEALTH OF VIRGINIA,
AND THE STATE OF WISCONSIN,
Ex. Rel
VEN-A-CARE OF THE FLORIDA KEYS, INC.
a Florida corporation,
and JOHN M. LOCKWOOD, M.D.

Plaintiffs,

v.

ASTRAZENECA LP,
ASTRAZENECA PHARMACEUTICALS LP,
ASTRA PHARMACEUTICALS LP,
ASTRAZENECA USA, INC.,
ASTRA USA, INC. and
ASTRAZENECA PLC.

Defendants.

CIVIL ACTION No.

FILED IN CAMERA
AND UNDER SEAL
PURSUANT TO 31 U.S.C. § 3730

**Complaint For Money Damages and
Civil Penalties Under the False Claims Act**

COMPLAINT FOR MONEY DAMAGES AND CIVIL PENALTIES
UNDER THE FALSE CLAIMS ACT 31 U.S.C. 03729-3732

The *qui tam* Relator, Ven-A-Care of the Florida Keys, Inc. ("Relator"), joined by its officer and director, John M. Lockwood, M.D., by and through its undersigned attorneys, on its own behalf and on behalf of the United States of America, the State of California, The State of Delaware, The District of Columbia, The State of Florida, The State of Georgia, The State of Hawaii, The State of Illinois, The State of Indiana, The State of Louisiana, The Commonwealth of Massachusetts, The State of Montana, The State of Nevada, The State of New Hampshire, The State of New Jersey, The State of New Mexico, The State of New York, The State of Rhode Island, The State of Oklahoma, The State of Tennessee, The Commonwealth of Virginia and the State of Wisconsin (hereinafter referred to collectively as the "States") brings this action against AstraZeneca LP, AstraZeneca Pharmaceuticals LP, Astra Pharmaceuticals, LP, AstraZeneca USA, Inc., Astra USA, Inc., and AstraZeneca PLC (collectively "AstraZeneca" or "Defendants") for violations of the Federal False Claims Act, 31 U.S.C. §3729 *et seq.*, as well as for violations of the following state false claims acts: The California False Claims Act, Cal. Gov't Code § 12650 *et seq.*; The District of Columbia False Claims Act, D.C. Code Ann. §2-308.03 *et seq.*; The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §1201 *et seq.*; The Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*; The Georgia False Claims Act, Official Code of Georgia Ann. § 49-4-168 *et seq.*; The Hawaii False Claims Act, Haw. Rev. Stat. §661-21 *et seq.*; The Illinois Whistleblower Reward and Protection Act, 740 Ill. Compo Stat. Ann. § 175/1 *et seq.*; The Indiana False Claims and Whistleblower Protection Act, Indiana Code §5-115.5; The State of Louisiana's Medical Assistance Programs Integrity Law, La. R.S. 46:437.1 *et seq.*; The Massachusetts False Claims Act, Mass. Ann. Laws. Ch. 12, §5A *et seq.*; The Montana False Claims Act, Mont. Code Anno. § 17-8-401 *et seq.*; The Nevada Submission of False Claims to State or Local Government, Nev.Rev. Stat. § 357.010 *et seq.*; The New Hampshire False Claims Act, RSA tit. XII, Ch. 167: 61-b; The New Mexico False Claims Act, N.M. Stat. Ann.

§ 27-14-1 *et seq.*; The New Jersey False Claims Act, N.J. Stat. Ann. §2A:32*Cet seq.*; The New York False Claims Act, NY CLS St. Fin. §187 *et seq.*; The Oklahoma False Claims Act, Okla. Code Ann. Stat. § 63-5053 *et seq.*; The Rhode Island False Claims Act, R.I. General Law § 9-1.1 *et seq.*; The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-171 *et seq.*; The Virginia Fraud Against Taxpayers Act, Va. Code §8.01-216.1 *et seq.* and the Wisconsin False Claims for Medical Assistance Act, Wis. Stats. §20.931 (hereinafter referred to as the "State False Claims Acts") to recover all damages, civil penalties and all other recoveries provided for under the Federal False Claims Act and the State False Claims Acts.

SECTION NO. I

SUMMARY OF THE ACTION

1. This is an action for damages, treble damages, restitution, civil penalties, prejudgment interest, equitable relief and for attorneys' fees and costs and expenses of the Relator against AstraZeneca LP, AstraZeneca Pharmaceuticals LP, Astra Pharmaceuticals, LP, AstraZeneca USA, Inc., Astra USA, Inc., and AstraZeneca PLC (collectively "AstraZeneca" or "Defendants") for ongoing violations of the Federal False Claims Act and the State False Claims Acts as set out in 1 through 64 herein.

2. AstraZeneca manufactures and distributes prescription drugs which are covered, for reimbursement purposes, by each state's Medicaid prescription drug reimbursement program ("State Prescription Drug Reimbursement Program"). To obtain such coverage, AstraZeneca was required by federal statute (42 U.S.C. § 1396r-8 (a)) to participate in the Medicaid Drug Rebate Program (the "Medicaid Drug Rebate Program") and entered into an agreement with the United States Secretary of the Department of Health and Human Services under the terms of which the drug manufacturer must pay a quarterly rebate to each state based on the number of units of each of the manufacturer's drug products that were reimbursed by the respective states. The amount of the rebate is determined by a formula specified in the federal Medicaid Drug Rebate Program statute which is based on drug sales price information that AstraZeneca is required to truthfully report to the Center for

Medicare and Medicaid Services of the United States Department of Health and Human Services (“CMS”). The Unit Rebate Amount (“URA”) of the Medicaid Drug Rebate Program rebates are calculated by CMS quarterly and then provided to the states. The State Prescription Drug Reimbursement Programs then calculate the number of units of each of the manufacturer’s drug products reimbursed during the applicable quarter and invoice the drug manufacturer for payment of the calculated rebate obligation. The drug sales price information supplied by AstraZeneca under the Medicaid Drug Rebate Program was also required to be used in setting the ceiling prices that would be paid by certain qualified public health providers under Section 340B of the Public Health Service Act (PHS Act). This case is based on AstraZeneca’s failure to provide truthful drug sales price information for its Nexium products which caused the Medicaid Drug Rebate Program rebates for certain Nexium products to be calculated significantly lower than they would have been had AstraZeneca provided truthful information. The United States and the States sustained damage due to AstraZeneca’s underpayment of rebates because the Medicaid Program is jointly funded by the federal and state governments. The United States and the States were further damaged to the extent that AstraZeneca charged government funded qualified entities prices in excess of the proper Section 340B ceiling prices.

3. Drugs fall within two classifications for Medicaid Drug Rebate Program purposes. One category consists of single source drugs and innovator multiple source drugs (hereinafter collectively referred to as “innovator drugs”) and generally includes all drugs first marketed under a New Drug Application (“NDA”) approved by the Food and Drug Administration. The remaining category consists of non-innovator multiple source drugs (hereinafter referred to as “non-innovator drugs”) and includes all those drugs marketed under an Abbreviated New Drug Application (“ANDA”) approved by the Food and Drug Administration. The drugs at issue herein have been classified as innovator drugs. As discussed in more detail herein, for Medicaid Drug Rebate Program purposes the quarterly Unit Rebate Amount is equal to the greater of (a) 15.1% of the Average Manufacturer Price (“AMP”) (this percentage increased as of 2010) or (b) the difference between the AMP and the Best Price. 42 U.S.C. 1396r-8 (c).

4. The Medicaid Drug Rebate Program relies on the drug manufacturer’s representations as to which of its drugs constitute different products because discounts given to the manufacturer’s best customers for

any package size of a drug product must be included in the rebate calculation for sales of all package sizes of the product. Under the applicable FDA regulations and policies, the drug manufacturer assigns the product code, which are numerals, specific to a particular drug product, that are included in the drug's National Drug Code number ("NDC"). See, 21 CFR §§ 207.25, 207.35. In this case, AstraZeneca assigned false product codes to its two Nexium products distributed in single dose "blister packs", when it should have assigned the same product codes that it assigned to the multi-dose bottle packages. Nexium is an innovator drug for Medicaid Drug Rebate Program purposes and it is particularly important that manufacturers truthfully report Best Prices which take into account discounts given on all package sizes of the same product. The law is very clear, Best Price ". . . shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package." 42 U.S.C. § 1396r-8(c) (1) (C) (ii) (II). This is to insure that the Medicaid Program will benefit from deep discounts given on any one package size of a product in the rebate calculations for all package sizes. Notwithstanding this clear requirement of the law, AstraZeneca falsely reported to the FDA, CMS and the State Prescription Drug Reimbursement Programs that its 20 MG and 40MG delayed release Nexium capsules in blister packs were different drug products than the delayed release Nexium capsules distributed in multi dose bottles. (The 20 MG and 40MG delayed release Nexium capsules are sometimes collectively referred to herein as the "Rebate Drugs.") AstraZeneca then falsely reported resulting false AMP and Best Prices to CMS and caused the reporting of the false Unit Rebate Amounts, derived from these AMP and Best Prices, to the State Prescription Drug Reimbursement Programs. As a result, AstraZeneca was charged and paid lower Medicaid Drug Rebate Program rebates to the State Prescription Drug Reimbursement Programs, to the detriment of both the Federal and State governments which jointly fund Medicaid. The Federal government's share of Medicaid funding is 50% or more for every state.

5. Nexium is a kind of drug known as a "proton pump inhibitor" which is intended to reduce the manufacture of stomach acid and thus help treat such conditions as acid reflux disease. The market for such drugs in the United States is huge and highly competitive. A significant portion of proton pump inhibitor prescriptions in the United States are reimbursed by the State Prescription Drug Reimbursement Programs and such drugs represent one of the largest categories, if not the largest, in

terms of total Medicaid dollars expended. Beginning in or before 2002 and continuing through at least 2009, AstraZeneca's false quarterly AMP and Best Price reports for its Nexium products distributed in multi-dose bottles failed to take into account material discounts given in connection with sales of individually wrapped packages of the same products made to certain key purchasers. The majority of Nexium prescriptions reimbursed by the State Prescription Drug Reimbursement Programs were for Nexium products sold in the multi-dose bottle packages. By falsely excluding the special discounts on the individually wrapped package sales from the AMP and Best Price calculations for the same products in larger package sizes, AstraZeneca misled the State Prescription Drug Reimbursement Programs, causing them to apply a much smaller Unit Rebate Amounts for most Nexium reimbursements than would have been applied had AstraZeneca truthfully reported the Nexium AMPs and Best Prices. AstraZeneca's false AMP and Best Price reports were made repeatedly, on at least a quarterly basis, and AstraZeneca further failed to correct its false reports through the Medicaid Drug Rebate Program reconciliation process which provided a clear and ongoing opportunity to do so. Instead, AstraZeneca exploited the inflated net after rebate cost of Nexium to the State Prescription Drug Reimbursement Programs by securing preferred drug status on many state Medicaid formularies through the payment of "supplemental rebates" which, in effect, merely provided some of the states with a portion of the rebate dollars they would have received anyway, but for the false AMP and Best Price reports.

6. The Defendants' actions alleged herein have caused the United States and the States to incur single damages collectively in excess of \$100,000,000.

SECTION NO. 2

THE PARTIES

7. The United States is a Plaintiff in this action. At all times material to this civil action, the United States Department of Health and Human Services ("HHS"), the Health Care Financing Administration ("HCFA"), and its successor agency the Centers for Medicare and Medicaid Services ("CMS") and The Bureau of Program Operations ("B.O.") were agencies and instrumentalities of the United States and its activities,

operations and contracts in administering the Medicaid program were paid from United States' funds.

8. The states, United States Territories, and the District of Columbia (collectively "the states") provide Medicaid benefits to qualified recipients which include payment of claims for the prescription drugs specified herein which were sold and marketed by AstraZeneca. A significant percentage (at least 50%) of Medicaid reimbursement for the Rebate Drugs was paid from United States Government funds. (42 U.S.C. § 1396(b)).

7. The Relator, Ven-A-Care, is a corporation organized under the laws of the State of Florida, with its principal offices in Key West, Florida. The Relator's principal officers and directors include John M. Lockwood, M.D., who is a citizen of the United States and resides in Key West, Florida. The Relator is a pharmacy and is licensed to provide the prescription drugs specified in this Complaint and has previously been a Florida Medicaid provider. The Relator has standing to bring this action pursuant to 31 U.S.C. §3730(b) (1). The information upon which these allegations are based was voluntarily provided by the Relator to the government prior to filing this Complaint.

8. The State of California ("California") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in California and were a covered Medicaid benefit under California's Medi-Cal Program.

9. The State of Delaware ("Delaware") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in the State of Delaware and were a covered Medicaid benefit under the State of Delaware's Medicaid Program.

10. The District of Columbia is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in the District of Columbia and were a covered Medicaid benefit under the District of Columbia's Medicaid Program.

14. The State of Florida ("Florida") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in Florida and were a covered Medicaid benefit under Florida's Medicaid Program.

15. The State of Georgia ("Georgia") is a Plaintiff in this action. Throughout the relevant time

periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in Georgia and were a covered Medicaid benefit under Georgia's Medicaid Program.

16. The State of Hawaii ("Hawaii") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in Hawaii and were a covered Medicaid benefit under Hawaii's Medicaid Program.

17. The State of Illinois ("Illinois") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in Illinois and were a covered Medicaid benefit under Illinois' Medicaid Program.

18. The State of Indiana ("Indiana") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in the State of Indiana and were a covered Medicaid benefit under the State of Indiana's Medicaid Program.

19. The State of Louisiana ("Louisiana") is a Plaintiff in this action. Throughout the relevant time periods specified herein, Defendants' Nexium drugs were provided to Medicaid recipients in the State of Louisiana and were a covered Medicaid benefit under the State of Louisiana's Medicaid Program.

20. The Commonwealth of Massachusetts ("Massachusetts") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in Massachusetts and were a covered Medicaid benefit under Massachusetts' Medicaid Program.

21. The State of Montana ("Montana") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in the State of Montana and were a covered Medicaid benefit under the State of Montana's Medicaid Program.

22. The State of Nevada ("Nevada") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in the State of Nevada and were a covered Medicaid benefit under the State of Nevada's Medicaid Program.

23. The State of New Hampshire ("New Hampshire") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in the State of New Hampshire and were a covered Medicaid benefit under the State of New Hampshire's

Medicaid Program.

24. The State of New Jersey ("New Jersey") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in New Jersey and were a covered Medicaid benefit under New Jersey's Medicaid Program.

25. The State of New Mexico ("New Mexico") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in New Mexico and were a covered Medicaid benefit under New Mexico's Medicaid Program.

25. The State of New York ("New York") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in the State of New York and were a covered Medicaid benefit under the State of New York's Medicaid Program.

26. The State of Hawaii ("Hawaii") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in Hawaii and were a covered Medicaid benefit under Hawaii's Medicaid Program.

27. The State of Oklahoma ("Oklahoma") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in Oklahoma and were a covered Medicaid benefit under Hawaii's Medicaid Program.

28. The State of Rhode Island ("Rhode Island") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in Hawaii and were a covered Medicaid benefit under Rhode Island's Medicaid Program.

29. The State of Tennessee ("Tennessee") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in Tennessee and were a covered Medicaid benefit under Tennessee's Medicaid Program.

30. The Commonwealth of Virginia ("Virginia") is a Plaintiff in this action. Throughout the relevant time periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in Virginia and were a covered Medicaid benefit under Virginia's Medicaid Program.

31. The State of Wisconsin ("Wisconsin") is a Plaintiff in this action. Throughout the relevant time

periods specified herein, AstraZeneca's Nexium drugs were provided to Medicaid recipients in Wisconsin and were a covered Medicaid benefit under Wisconsin's Medicaid Program.

31. Defendants, AstraZeneca Pharmaceuticals, LP, AstraZeneca LP, Astra Pharmaceuticals, LP, Astra USA, Inc. and AstraZeneca USA, Inc are headquartered in Wilmington, Delaware, and are part of the large international pharmaceutical conglomerate of AstraZeneca PLC, based in the United Kingdom. AstraZeneca PLC was formed in 1999 through the merger of Zeneca Group PLC of the United Kingdom with Astra AB of Sweden. From 1998 until the merger in 1999, AstraZeneca Pharmaceuticals, LP served as the US subsidiary of Astra AB. AstraZeneca Pharmaceuticals, LP and AstraZeneca LP, are entities through which the Nexium products at issue in this case were marketed and distributed in the United States and the entities responsible for truthfully reporting information required under the Medicaid Drug Rebate Program. The manufacturer labeler code under which the Nexium products were marketed , 001086, was assigned by the FDA to "AstraZeneca" and the false product codes, contained in the NDCs for the Nexium products at issue in this case, were secured by AstraZeneca agents or employees acting on behalf of AstraZeneca Pharmaceuticals, LP, AstraZeneca LP, Astra USA, Inc. and AstraZeneca USA, Inc. AstraZeneca, Astra USA, Inc., AstraZeneca Pharmaceuticals LP, AstraZeneca LP and Astra Pharmaceuticals Products, Inc. have, at various times, identified themselves to the US Public Health Service, the FDA, CMS and the State Prescription Drug Reimbursement Programs as marketing drugs under Labeler Code 00186 and are responsible for the false statements and records and false claims alleged herein. By way of example, the most recent CMS file of Medicaid Drug Rebate Program manufacturer contacts, identifies three employees of AstraZeneca LP (who otherwise hold themselves out as Senior Counsel, Corporate Compliance and Audit Manager and Senior Brand Forecasting Manager/ formerly Sr. Manager, Government Pricing & Analytics) as the corporate officials of AstraZeneca LP responsible for Medicaid Drug Rebate Program matters. Similarly, the records of the US Public Health Service reflect that corporate officials of Astra Pharmaceuticals LP, (upon information and belief the successor to AstraZeneca Pharmaceuticals LP) are responsible for dealing with the government with respect to drugs marketed under Labeler Code 00186, which includes the Nexium products at issue in this case. To the extent the acts of one Defendant at issue herein were performed by or otherwise attributable to another Defendant or any subsidiary or affiliate of a Defendant, then judgment

should be entered against such Defendants where appropriate, including AstraZeneca PLC. At all times material to this civil action, AstraZeneca transacted business in the Federal Judicial District of New Hampshire by, including but not limited to, selling and distributing its drugs, including those identified in this Complaint, to purchasers within the District of New Hampshire; including but not limited to, selling directly or through wholesalers its specified prescription drugs in the District of New Hampshire knowing that the drugs would be supplied to Medicaid recipients and for which claims would be paid from Medicaid funds.

32. Any and all acts alleged herein to have been committed by any or all of the Defendants were committed by said Defendants' officers, directors, employees, or agents who at all times acted on behalf of its respective Defendants.

SECTION NO. 3

JURISDICTION & VENUE

33. Jurisdiction, which also expressly encompasses the actions under State False Claims Acts, is founded upon the Federal False Claims Act (the "Act" or the "False Claims Act"), 31 U.S.C. §3729-32, specifically 31 U.S.C. §3732, and also 28 U.S.C. §1331, 1345.

34. Venue in the District of New Hampshire is appropriate under 31 U.S.C. §3732(a) and sufficient contacts exist for jurisdiction in that AstraZeneca transacted business in the District of New Hampshire by selling directly or through wholesalers its prescription drugs, including those identified in this Complaint, in the District of New Hampshire. Such drugs, as AstraZeneca knows, 1) have been and continue to be supplied to Medicaid recipients and 2) have been and continue to be the subject of claims for reimbursement by the New Hampshire Medicaid Program made by Medicaid prescription drug providers, including pharmacies.

35. On or about August 5, 2010, the Relator's officer and director, John Lockwood, acting through and with the assistance of counsel, voluntarily provided the information and allegations on which this Complaint is based to the United States government. The Complaint was subsequently filed in camera and under seal, as required by 31 USC§3730 (b) (2), and a copy of this initial Complaint and written disclosure of substantially all material evidence and information the Relator possesses were served on the Government pursuant to

(Rule 4(i)(1)(A) and (B) (formerly Rule 4 (d)(4)), Fed.R.Civ.P., by delivering a copy of this Complaint and a written disclosure of substantially all material evidence and information the Relator possesses, to the United States Attorney for the District of New Hampshire and by sending a copy of this Complaint, material evidence and information by certified mail to the Attorney General of the United States at Washington, District of Columbia.

SECTION NO. 4

ASTRAZENECA'S FRAUD IN CONNECTION WITH THE MEDICAID DRUG REBATE PROGRAM

A. BACKGROUND OF THE STATE MEDICAID PRESCRIPTION DRUG COVERAGE PROGRAM AND THE REBATE PROGRAM

36. The United States Government partially funds state sponsored medical assistance programs for the poor pursuant to Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq. (referred to herein as the "Medicaid Program"). The Federal government enacted the Medicaid Program in 1965 as a cooperative undertaking between the Federal and State governments. Each State administers its own Medicaid program, but the States' programs are governed by Federal statutes, regulations and guidelines.

37. Benefits for drugs are optional but all States have opted to provide Medicaid drug reimbursement coverage.

38. The federal portion of each State's Medicaid payments, Federal Medical Assistance Percentage ("FMAP"), is based on that State's per capita income compared to the national average. The federal portion consists of a minimum of 50% up to a maximum of 83%. For example, Florida's FMAP contributed by the United States in 1995 was 56.28%. (42 U.S.C. § 1396b).

39. The states, United States Territories and the District of Columbia are required to implement a State Health Plan containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. §1396a (a)(30)(A).

40. State Health Plans must, in part, provide for payment of claims for prescription drugs pursuant to a formula approved by the Secretary of Health and Human Services which determines the maximum

allowable claim amount for each drug manufactured by each manufacturer whose prescription drugs qualify for Medicaid reimbursement based upon an estimation of the provider's acquisition cost plus a reasonable dispensing fee. 42 CFR §447.331.

41. After hearings in 1989, Congress concluded that the Federal government, as the largest payor for prescription drugs, was paying significantly more under the State's Medicaid Programs than certain private payors. See, e.g. Skyrocketing Drug Prices: Hearings Before the Special Committee before the United States Senate, 101th Congress, 290-297 (1989).

42. Congress addressed this inequity in the Omnibus Budget Reconciliation Act of 1990, which established the Medicaid Drug Rebate Program. PL-101-508, 104 Stat. 1388 (1990). The stated purpose of the Rebate Program was to give the State Medicaid Programs the "benefit of the best price for which a manufacturer [sold] a prescription drug to any. . . private purchaser." H.R. Rep. No. 101-881, at 96 (1990).

43. The Medicaid Drug Rebate Program requires all manufacturers, whose drugs are paid for by Medicaid, to enter into an agreement with the Secretary of the Department of Health and Human Services, under which the manufacturer agrees to pay each State a quarterly rebate. The amount received by a State in rebates is considered a reduction in the total amount expended under any given State's plan. Therefore, the less any given State receives in rebates, the greater the total amount expended by that specific State and the more the Federal government must correspondingly pay to that State (because the Federal government contributes a set percentage of the total amount each State expends on Medicaid). 42 U.S.C. 1396b (a) (1); 42 U.S.C. 1396r-8(b)(1)(B).

Basic Rebate Amount Calculation

44. Under the Medicaid Drug Rebate Program, 42 U.S.C. § 1396r-8(c)(1)(A) and (B), each State's basic rebate amount for each quarterly (three month) rebate period for each dosage form and strength of a single source drug or innovator multiple source drug (collectively the "innovator drugs") has been equal to the

product of:

- (a) The total number of units of each dosage form and strength paid for under the State Medicaid drug reimbursement plan in the rebate period (as reported by the State); and
- (b) the greater of the difference between the "Average Manufacturer Price" ("AMP") minus the manufacturer's "Best Price" ("BP") for the dosage form and strength of the drug or the minimum rebate percentage of the AMP (the minimum rebate percentage has been 15.1% since January 1, 1996)¹.

"Best Price" Calculation

45. The Medicaid Drug Rebate Program statute, 42 U.S.C. §1396r-8(c)(1)(C), explicitly defines Best Price as the following:

- (i) The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity within the United States, excluding - -
 - (I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, United States Code, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B);
 - _____any prices charged under the Federal Supply Schedule of the General Services Administration;
 - (III) any prices used under a State pharmaceutical assistance program; and
 - (IV) any depot prices and single award contract prices, as defined by

¹ Prior to that date, the minimum rebate percentage was as follows:

- (i) 12.5 percent after December 31, 1990, and before October 1, 1992;
- (ii) 15.7 percent after September 30, 1992, and before January 1, 1994;
- (iii) 15.4 percent after December 31, 1993, and before January 1, 1995;
- (iv) 15.2 percent after December 31, 1994 and before January 1, 1996.
- (v)

the Secretary, of any agency of the Federal Government.

(ii) Special rules. The term "best price" - -

- (I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);
- (II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and
- (III) shall not take into account prices that are merely nominal in amount.

Best Price Exclusion — Nominal Price

46. For Best Price exclusion purposes, a price that is "merely nominal in amount," in other words a "nominal price," is "a price that is less than 10 percent of AMP." See Medicaid Program: Payment for Covered Outpatient Drugs Under Drug Rebate Agreements With Manufacturers, 60 Fed. Reg. 48442 (Sept. 19, 1995)(hereinafter "60 Fed. Reg. 48442"); see also the rebate agreement entered into between Secretary of the Department of Health and Human Services and drug manufacturers participating in the Medicaid Drug Rebate Program.

47. The determination of whether or not a drug included in a "Bundled Sale," is nominally priced, must be made after the proportionate allocation of any discount in that bundle, *see* paragraphs 48 through 50 below.

Best Price and Bundled Sales

48. Pursuant to Medicaid regulations and the terms of the Medicaid Rebate Agreement entered into between drug manufacturers and the Secretary of the Department of Health and Human Services, for "best price" calculations in the context of bundled sales, the discount must be allocated proportionately to the dollar value of the units of each drug sold under the bundled agreement. Bundled sales, a common industry practice among drug manufacturers, are sales in which the condition for a rebate or discount to be given is that two or more different drug products are purchased together, or in which the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.

49. Proportionate allocation of discounts within a bundle is required when calculating the

correct rebate amount which Defendants should have paid as to its drugs; particularly the Nexium drugs at issue (referred to herein at times as the "Rebate Drugs"). To properly determine the Best Price for each such Rebate Drug for each quarter, it must be determined whether or not the Rebate Drug was ever sold in a bundle during such quarter. If so, the proportionate impact of any discounts on any drugs in such bundles on the Best Price of the given Rebate Drug must be calculated.

50. Proportionate allocation of discounts within a bundle also is required with respect to any innovator drugs which were bundled with a Rebate Drug. The higher the reported Best Price, the smaller the rebate due on an innovator drug up to the amount based on the minimum of 15.1% of AMP. Throughout the time periods specified herein, the Best Price of any innovator drug bundled with a Rebate Drug (hereinafter referred to as "the Bundled Drugs") was required to be calculated by proportionately allocating all discounts among all drugs in the bundle. Therefore, to the extent the Defendants did not allocate the discount on a Rebate Drug proportionately within a bundle, they necessarily reported a falsely inflated best price for any Bundled Drug.

AMP Calculation

51. Pursuant to 42 U.S.C. §1396r-8(k)(1), AMP means, during the rebate period, "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts."

52. For each dosage form and strength of an innovator drug, manufacturers must also pay an additional rebate based upon the amount, if any, by which the drug's AMP has risen (for the calendar quarter beginning with the latter of either July 1, 1990 or the time the drug was first marketed) more quickly than the rate of inflation as determined by reference to the national Consumer Price Index for urban consumers ("CPIU"). 42 U.S.C. §1396r-8(c)(2)(A).

Calculation of Rebate Amount Due to Each State

53. The Medicaid Rebate statute states that each State's basic rebate for all

other prescription (non-innovator) drugs has been equal to the product of:

(A) In general

- (i) the applicable percentage (as described in subparagraph (B)) of the AMP for the dosage form and strength for the rebate period, and
- (ii) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State Medicaid drug reimbursement plan for the rebate period.

(B) "Applicable percentage" defined

For purposes of subparagraph (A) (i), the "applicable percentage" for rebate periods beginning -

- (i) before January 1, 1994, is 10 percent, and
- (ii) after December 31, 1993, is 11 percent.

42 U.S.C. §1396r-8(c)(3)(A) and (B).

54. Manufacturers report its AMP's and Best Price's to CMS on a quarterly basis. CMS, in turn, calculates the rebate amount as either AMP minus BP (or uses the current 15.1% minimum) for innovator drugs or AMP multiplied by 11% (or 10% prior to 1994) for non-innovator drugs and considers the CPIU as compared to any rise in the AMP of each innovator drug. CMS then forwards the figures by NDC number (the identification number for each dosage and unit size for each drug) to each state. Each state then multiplies the rebate amount by the number of units that the state paid for during the quarter for each NDC number to determine the rebate amount due and submits this amount to the manufacturer for payment. The manufacturer remits this payment on a quarterly basis, withholding any disputed amount.

Importance of Classification by Drug Manufacturers of Drugs, Identified by NDC Number, As Different Products When Those NDCs Are Actually Merely Different Package Forms

55. Of particular importance to the allegations at hand, when calculating Medicaid rebates, AstraZeneca was and is required to calculate both AMPs and Best Prices without regard

for differences in package sizes of a given drug product. This requirement was expressly set forth in the Medicaid Drug Program Rebate Agreement which drug manufacturers, such as AstraZeneca, executed with the Secretary of Health and Human Services of the United States. *Rebate Agreement* pp. 1-2. Indeed, Congress emphasized in the pertinent federal law that Best Price “. . . shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package.” 42 U.S.C. § 1396r-8 (c)(1) (C) (ii)(II). The federal agency governing the Medicaid program further reiterated this point publicly in or about 1991 in noting in a sentence (which was bolded and underlined for emphasis in the original) stating, **“Remember that HCFA relies on the individual manufacturers or labelers to furnish the correct information for each drug product.”**

**B. ASTRAZENECA FALSELY IDENTIFIED CERTAIN NEXIUM
DRUGS TO THE FEDERAL GOVERNMENT AS DIFFERENT
“PRODUCTS” WITH UNIQUE PRODUCT CODES, WHEN THEY WERE
MERELY DIFFERENT PACKAGE SIZES OF THE SAME PRODUCT**

56. Throughout the periods specified herein, AstraZeneca: 1) knew that CMS used the information AstraZeneca supplied to it to calculate the rebate amounts, 2) knew that CMS transmitted the rebate amounts it had calculated to the State Medicaid Programs which then multiplied those figures by the number of units reimbursed for of each drug and 3) knowingly, as that term is defined in 31 U.S.C. § 3729(b), supplied to CMS the false AMPs, Best Prices and Product Codes as alleged in this Complaint.

57. At all times relevant to this Complaint, AstraZeneca has taken advantage of the fact that the Medicaid Drug Rebate Program rebate amounts calculated for Nexium would be less if AstraZeneca improperly classified certain discounted sales as being of different drug “products. AstraZeneca accomplished this by falsely reporting, to the FDA, CMS and the State Prescription Drug Reimbursement Programs, that certain unit dose packages of the Nexium Rebate Drugs were different products than Nexium sold in bottles or in bulk when, in fact, they were only different packages of the same products. For Medicaid Drug Rebate Program purposes, AstraZeneca was required to include all packages of the same Nexium product formulations

and strengths in the AMPs and Best Prices it reported for use in Unit Rebate Amount calculations which AstraZeneca knew are the basis for all Medicaid rebates paid on the Rebate Drugs. Instead, AstraZeneca falsely represented that different package sizes of the same Nexium products were different products in order to secure different product codes in the FDA National Drug Codes (NDCs) and then used the false Nexium NDCs in reporting false AMPs and Best Prices.

AstraZeneca thus falsely represented to CMS that Nexium sold under the false NDCs were different products when in reality they were merely differently packaged (ie. individually-wrapped “blister pack”) versions of the same Nexium products that were sold in multi-dose bottle and bulk packages. Specifically, AstraZeneca falsely utilized product codes of 5022 and 5042 when it was required to assign the existing Nexium 20MG delayed release capsule product code of 5020 and the existing Nexium 40MG delayed release capsule product code of 5040 for its “blister-pack” versions of these identical Nexium products. The following chart summarizes these allegations:

AstraZeneca's False Assignment of Nexium Product Codes

NDC Number	False Product Code Assigned by AZ	Actual Product Formulation	Package Format/Size of Product	Proper Product Code
00186502228	5022*	Nexium 20 mg	individually wrapped	5020
00186504228	5042*	Nexium 40 mg	individually wrapped	5040
00186502031	N/A	Nexium 20 mg	bottle of 30	5020
00186502054	N/A	Nexium 20 mg	bottle of 90	5020
00186502082	N/A	Nexium 20 mg	bottle of 1000	5020
00186504031	N/A	Nexium 40 mg	bottle of 30	5040
00186504054	N/A	Nexium 40 mg	bottle of 90	5040
00186504082	N/A	Nexium 40 mg	bottle of 1000	5040
* These false product classifications by AZ were made in conjunction with AZ wrongly excluding discounted sales of 20mg and 40mg Nexium sold in “blister packs” from its calculations of BPs and AMPs for those respective 20mg and 40 mg products (ie., strengths).				

58. AstraZeneca acted knowingly, as that term applies under the False Claims Act and the State False Claims Acts, in falsely providing the false information to the FDA, CMS and the State Prescription Drug Reimbursement Programs as alleged in this Complaint in that AstraZeneca acted with

actual knowledge; reckless disregard of the truth or falsity or deliberate ignorance of the truth or falsity of the information. AstraZeneca operates a successful and sophisticated international pharmaceutical manufacturing and marketing enterprise and is knowledgeable about and able to comply with FDA requirements regarding assignments of “Product Codes” and Medicaid Drug Rebate Program requirements regarding AMP and Best Price reporting. AstraZeneca’s Swedish sister corporation, AstraZeneca AB, assigned common product codes for Nexium products as required by the FDA. AstraZeneca’s joint venture partner Merck, secured NDCs to market Prilosec, the AstraZeneca predecessor product to Nexium, and assigned the same product code to Prilosec distributed in single dose blister packs as it assigned to the same product distributed in different packaging. This year, AstraZeneca secured NDCs for Vimovo Tablets, which contains Esomeprazole Magnesium, the same molecule as Nexium, and assigned the same product codes to the blister pack versions as it did the same products in bottles. During the period at issue in this Complaint, Nexium was extremely significant to AstraZeneca in terms of sales and profits and State Prescription Drug Reimbursement Programs collectively were a principle source of Nexium revenue, if not the largest payor for the drug. Indeed, AstraZeneca repeatedly exploited the high net (after rebate) cost of Nexium to the State Prescription Drug Reimbursement Programs, resulting from its underpayment of amounts owed under the Medicaid Drug Rebate Program, in persuading the states to assign Nexium preferred drug status in exchange for payments of supplemental rebates to certain states. AstraZeneca’s knowledge is further shown by its repeated quarterly false AMP and Best Price reports, followed by its failure to take corrective actions in the ongoing Medicaid Drug Rebate Program reconciliation process with each state’s Medicaid Program. Through its quarterly submissions to CMS regarding the Rebate Drugs, AstraZeneca: (A) knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval; (B) knowingly made, used, or caused to be made or used, false records and statements material to false or fraudulent claims; and (C) knowingly made, used, or caused to be made or used, false records and statements material to obligations to pay or transmit money or property to the Government, or

knowingly concealed or knowingly and improperly avoided and decreased an obligation to pay or transmit money or property to the Government.

59. AstraZeneca's quarterly representations of false product, AMP and Best Price information to CMS enabled the AstraZeneca to pay, and caused the states to collect amounts under the Medicaid Drug Rebate Program, that were substantially less than AstraZeneca otherwise owed and, in turn, caused the states to submit to the United States, and the United States to pay, quarterly claims for federal matching dollars ("FMAP") that were substantially greater than they would have been but for the AstraZeneca's false information. AstraZeneca further acted with knowledge that the false information would cause the underpayment of rebates to the States under the Medicaid Drug Rebate Program and, in turn, cause the overpayment of FMAP amounts by the United States. Accordingly, AstraZeneca's actions constitute violations of the False Claims Act (specifically the provisions of 31 U.S.C. §3729(a)(1)(A),(B) and (G); formerly 31 U.S.C. §3729(a)(1), (a)(2) and (a)(7)), and the comparable provisions of the State False Claims Acts, for reasons which include, but are not necessarily limited to, the following:

- a.) AstraZeneca knowingly caused each of the State Medicaid Programs to present false or fraudulent claims to the United States for quarterly FMAP payments from in or before 2002 through at least 2009.
- b.) AstraZeneca knowingly made or used and caused to be made or used false records and false statements, material to the false or fraudulent FMAP claims by the states, in order to get false or fraudulent claims paid or approved.
- c.) AstraZeneca knowingly made or used, or caused to be made or used, false records or statements material to the obligations to pay amounts to the states under the Medicaid Drug Rebate Program, concealing the extent of and reducing the amounts of the Medicaid Drug Rebate Program payments to the states and, in turn, material to the state's FMAP related reports, resulting in increased FMAP payments by the United States to the states

and in concealed credits which would have otherwise reduced the FMAP obligations of the United States.

60. As a result of the AstraZeneca's fraudulent course of conduct, the United States and State governments have suffered actual damages in excess of One Hundred Million Dollars (\$100,000,000.00), all in violation of the False Claims Act and the State False Claims Acts.

SECTION NO. 5

ASTRAZENCA'S FRAUD IN CONNECTION WITH THE SECTION 340B DRUG PRICING PROGRAM

61. Section 340B of the Public Health Service Act (42 U.S.C. § 256b). provides for a drug pricing program whereby certain qualified public health providers ("qualified 340B entities") are charged drug prices that cannot exceed ceiling prices calculated pursuant to the law ("the 340B Ceiling Prices"). AstraZeneca opted to participate in the Section 340B Program and thus agreed to sell its drugs, including Nexium, to qualified 340B entities at prices that did not exceed the 340B Ceiling Prices. The 340B Program requires manufacturers to enter into a Pharmaceutical Pricing Agreement (PPA) with the Secretary of the Department of Health and Human Services.

62. Section 340B qualified entities include such health providers as community health centers, public housing clinics and school based programs that are often funded by the state or federal governments.

63. 340B Ceiling Prices are calculated based on the Best Price and AMP information the drug manufacturer supplies to CMS as part of the Medicaid Drug Rebate Program. Drug manufacturers are required to calculate its drugs' applicable 340B Ceiling Prices, on a smallest dispensable unit basis, by, in effect, subtracting the URA from the AMP. Manufacturers must make the 340B Ceiling Prices available to all qualified 340B entities whether the drugs are sold directly or through wholesalers. In the

event that a qualified 340B entity pays more than the 340B Ceiling Price, the manufacturer must refund the difference.

64. AstraZeneca knew that it was required under the 340B Program (42 U.S.C. § 256b) to charge prices for Nexium that were at or below the 340B Ceiling Prices to qualified 340B entities and that AstraZeneca was required to calculate the 340B Ceiling Prices for Nexium quarterly by subtracting the Unit Rebate Amount from the Average Manufacturer's Price for each Nexium product. AstraZeneca's actions in overstating the Best Prices for the sales of Nexium multi-dose bottle packages caused a corresponding increase in the 340B Ceiling Prices for Nexium. AstraZeneca overcharged qualified 340B providers each and every time it charged more for Nexium than the truthful 340B Ceiling Price calculated on the basis of truthful Best Price and URA information. Accordingly, each time AstraZeneca overcharged, or caused a wholesaler to overcharge, a qualified 340B Provider that was funded by or an agency or instrumentality the United States and/or a State, AstraZeneca presented or caused the presentment of a false or fraudulent claim for payment or approval, and made or used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved. In addition, each time AstraZeneca failed to provide or arrange for a discount, refund, credit or rebate sufficient to lower the net amount paid for Nexium by a qualified 340B Provider that was also funded by or an agency or instrumentality of the United States and/or a State, AstraZeneca made, used or caused to be made or used, a false record or statement to conceal, avoid or decrease an obligation to transmit money or property to the state or federal government and the false record or statement was material to and concealed its obligation to pay or transmit money or property to the state or federal government.

COUNT 1

**VIOLATIONS OF UNITED STATES FALSE CLAIMS ACT; PRESENTING OR CAUSING
THE PRESENTMENT OF FALSE OR FRAUDULENT CLAIMS FOR PAYMENT OR
APPROVAL**

65. This is a civil action by the Plaintiff, United States, and the Relator, Ven-A-Care, on behalf of the United States and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, ("AstraZeneca") under the False Claims Act, 31 U.S.C. §3729-3732.

66. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

67. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in 31 U.S.C. §3729(b)(1)] presented, or caused to be presented to an officer or employee of the Government, false or fraudulent claims for payment or approval, in that AstraZeneca submitted false information to the FDA and, thereafter, to CMS and the State Prescription Drug Reimbursement Programs on a quarterly basis, as set forth herein, including, but not necessarily limited to, that the Nexium products sold in single dose packages were different products than those of the same strength, sold in multi-dose bottles and, submitted false reports to CMS wherein discounted sales of Nexium in single dose packages were falsely excluded from AMP and Best Price calculations for sales in multi-dose bottle packages. By reporting this false and fraudulent information, as well as any inflated Best Prices for Bundled Drugs, AstraZeneca caused reductions in the quarterly calculated Unit Rebate Amounts for sales of Nexium in multi-dose bottle packages and corresponding reductions of the amounts of AstraZeneca's payments under the Medicaid Drug Rebate Program to the states. AstraZeneca's false and fraudulent information caused the periodic calculations of drug reimbursement costs prepared and submitted by each state's Medicaid Program to the federal government pursuant to 42 U.S.C. § 1396(b) ("the Submissions") to be inflated and false or fraudulent. The inflated Submissions in turn caused the federal government to overpay the federal matching payments

("FMAP") to each state's Medicaid program. The Submissions thereby each constitute a false or fraudulent claim pursuant to the False Claims Act, 31 U.S.C. §3729(a) (1) (A) (formerly 31 U.S.C. §3729(a) (1)).

68. AstraZeneca knew that the information it supplied to CMS was utilized by the United States and the state Governments to determine the required amount of rebate owed to each state's Medicaid Program for each of its Rebate Drugs. By submitting the false information at issue here, AstraZeneca fraudulently reduced and underpaid amounts it owed the Medicaid Drug Rebate Program for Nexium and caused each state's Submissions for matching funds to the United States, to be false or fraudulent claims, thus resulting in great financial loss to the United States.

69. AstraZeneca also knew that it was required under the 340B Drug Pricing Program (340B Program), to charge prices for Nexium that were at or below statutorily defined prices, known as the 340B Ceiling Prices, to qualified 340B entities and that AstraZeneca was required to calculate the 340B Ceiling Prices for Nexium quarterly by subtracting the Unit Rebate Amount from the Average Manufacturer's Price for each Nexium product. To the extent that AstraZeneca's actions in overstating the Best Prices for the sales of Nexium multi-dose bottle packages caused a corresponding increase in the 340B Ceiling Prices for Nexium, AstraZeneca presented or caused the presentment of a false or fraudulent claim each time AstraZeneca or a wholesaler charged a qualified 340B entity, funded by or an agency or instrumentality of the government, an amount above the 340B Ceiling Price that would have been calculated, but for AstraZeneca's false and fraudulent information about the Best Prices of the Nexium products.

70. Because of Defendant AstraZeneca's conduct as set forth in this Count, the United States suffered actual damages in excess of Ten Million Dollars (\$10,000,000), all in violation of 31 U.S.C. §3729(a).

COUNT 2

**VIOLATIONS OF UNITED STATES FALSE CLAIMS ACT;
MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR
STATEMENT MATERIAL TO A FALSE OR FRAUDULENT CLAIM
AND
MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR
STATEMENT TO GET A FALSE OR FRAUDULENT CLAIM PAID BY THE
GOVERNMENT**

68. This is a civil action by the Plaintiff, United States, and the Relator, Ven-A-Care, on behalf of the United States and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, (“AstraZeneca”) under the False Claims Act, 31 U.S.C. §3729-3732.

69. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

69. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in 31 U.S.C. §3729(b)(1)] made or used , or caused to be made or used, false records and statements material to a false or fraudulent claim in that AstraZeneca submitted false information to the FDA and, thereafter, to CMS and the State Prescription Drug Reimbursement Programs on a quarterly basis, as set forth herein, including, but not necessarily limited to, that the Nexium products sold in single dose packages were different products than those of the same strength, sold in multi-dose bottles and, thereafter submitted false reports to CMS wherein discounted sales of Nexium in single dose packages were falsely excluded from AMP and Best Price calculations for sales in multi-dose bottle packages. By making, and causing to be made, these false records and statements, AstraZeneca caused reductions in the quarterly calculated Unit Rebate Amounts for sales of Nexium in multi-dose bottle packages and corresponding reductions of the amounts of AstraZeneca’s payments under the Medicaid Drug Rebate Program to the states. AstraZeneca’s false records and statements caused the periodic calculations of drug reimbursement costs, prepared and submitted by each state’s Medicaid Program to the federal government pursuant to 42 U.S.C. § 1396(b) (" the

Submissions"), to be inflated and false or fraudulent. The inflated Submissions in turn caused the federal government to overpay the federal matching payments ("FMAP") to each State's Medicaid program. The Submissions thereby each constitute a false record or statement, caused to be made by AstraZeneca, material to a false or fraudulent claim pursuant to the False Claims Act, 31 U.S.C. §3729(a) (1) (B).

70. AstraZeneca knew that the information it supplied to CMS was material to the United States' and the State Governments' determination of the required amount of rebate owed to each State's Medicaid Program for each of its Rebate Drugs. AstraZeneca fraudulently reduced and underpaid amounts it owed the Medicaid Drug Rebate Program for Nexium and caused each State's Submissions for matching funds to the United States, to be false or fraudulent claims, thus resulting in great financial loss to the United States.

71. AstraZeneca also knew that it was required under the 340B Drug Pricing Program (340B Program), to charge prices for Nexium that were at or below statutorily defined prices, known as the 340B Ceiling Prices, to qualified 340B entities and that AstraZeneca was required to calculate the 340B Ceiling Prices for Nexium quarterly by subtracting the Unit Rebate Amount from the Average Manufacturer's Price for each Nexium product. To the extent that AstraZeneca's actions in overstating the Best Prices for the sales of Nexium multi-dose bottle packages caused a corresponding increase in the 340B Ceiling Prices for Nexium, AstraZeneca made or used, or caused to be made or used, a false record or statement, material to a false or fraudulent claim, to get a false or fraudulent claim paid or approved by the Government each time AstraZeneca or a wholesaler charged a qualified 340B entity, funded by or an agency or instrumentality of the government, an amount above the 340B Ceiling Price that would have been calculated, but for AstraZeneca's false records or statements about the Best Prices and Unit rebate Amounts of the Nexium products.

71. Because of Defendant AstraZeneca's conduct as set forth in this Count, the United States suffered actual damages in excess of Ten Million Dollars (\$10,000,000), all in violation of 31 U.S.C. §3729(a) (1) (B) (formerly 31 U.S.C. §3729(a) (2)).

COUNT 3

**VIOLATIONS OF UNITED STATES FALSE CLAIMS ACT;
MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR
STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR
TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT,
AND
MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR
STATEMENT MATERIAL TO AN OBLIGATION TO PAY OT TRANSMIT MONEY OR
PROPERTY TO THE GOVERNMENT, AND
CONCEALING AN OBLIGATION TO PAY OR TRANSMIT MONEY TO THE
GOVERNMENT**

72. This is a civil action by the Plaintiff, United States, and the Relator, Ven-A-Care, on behalf of the United States and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, (“AstraZeneca”) under the False Claims Act, 31 U.S.C. §3729-3732.

73. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

74. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in 31 U.S.C. §3729(b)(1)] made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government in that AstraZeneca submitted false information to the FDA and, thereafter, to CMS and the State Prescription Drug Reimbursement Programs on a quarterly basis, as set forth herein, including, but not necessarily limited to, that the Nexium products sold in single dose packages were different products than those of the same strength, sold in multi-dose bottles and, thereafter submitted false reports to CMS wherein discounted sales of Nexium in single dose packages were falsely excluded from AMP and Best Price calculations for sales in multi-dose bottle packages. By making, and causing to be made, these false records and statements, AstraZeneca caused reductions in the quarterly calculated Unit Rebate Amounts for sales of Nexium in multi-dose bottle packages and corresponding reductions of the amounts of AstraZeneca’s payments under the Medicaid Drug Rebate Program to the states, which payments were to benefit the United States

in accordance with each states' respective FMAP percentage. Accordingly, AstraZeneca's false records and statements were made to conceal, avoid or reduce an obligation to pay or transmit money to the government.

75. AstraZeneca's false records and statements were also material to the determination of, and concealed, its Medicaid Drug Rebate Program obligations to pay or transmit money or property to the government.

76. AstraZeneca's false records and statements further caused the periodic calculations of drug reimbursement costs, prepared and submitted by each state's Medicaid Program to the federal government pursuant to 42 U.S.C. § 1396(b) ("the Submissions"), to be inflated and resulted in the United states receiving credits in its FMAP calculations with the states that were less than they would have been, but for AstraZeneca's false records and statements. The inflated Submissions in turn caused the federal government to overpay the federal matching payments ("FMAP") to each State's Medicaid program. The Submissions thereby each constitute a material false record or statement, caused to be made by AstraZeneca, that decreased or concealed the states' obligations to pay or transmit money or property to the Government pursuant to the False Claims Act, 31 U.S.C. §3729(a) (1)(G) (formerly 31 U.S.C. §3729(a) (7)) .

77. AstraZeneca further knowingly made or used, or caused to be made or used ,a material false record or statement that decreased, avoided and concealed an obligation to pay or transmit money or property to the government, each time it invoiced a qualified 340B entity, funded by or an agency or instrumentality of the government, amounts for Nexium in excess of the 340B Ceiling Price and then failed to refund, or cause to be refunded, an amount sufficient to reduce the total amount paid to the 340B Ceiling Price.

78. Because of Defendant AstraZeneca's conduct as set forth in this Count, the United States and the State Governments suffered actual damages in excess of Ten Million Dollars (\$10,000,000), all in violation of 31 U.S.C. §3729(a) (1)(G) (formerly 31 U.S.C. §3729(a) (7)) .

COUNT 4

VIOLATIONS OF CALIFORNIA FALSE CLAIMS ACT; PRESENTING OR CAUSING THE PRESENTMENT OF FALSE OR FRAUDULENT CLAIMS FOR PAYMENT OR APPROVAL

79. This is a civil action by the Plaintiff, California, and the Relator, Ven-A-Care, on behalf of California and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, (“AstraZeneca”) under the under the California False Claims Act.

80. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

81. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in Cal. Gov’t Code §12650(b)(2)] presented or caused to be presented false or fraudulent claims to the California Medicaid Program, in that AstraZeneca submitted false information to the FDA and, thereafter, to CMS and the California Medicaid Program on at least a quarterly basis, as set forth herein, regarding its Rebate Drugs, including whether each NDC was a different Nexium product or not. By reporting this false information, as well as any inflated Best Prices for Bundled Drugs, AstraZeneca improperly reduced its rebate amounts and underpaid the rebate it owed to the California Medicaid Program each time it submitted rebate information and payments to the California Medicaid Program (“the California Medicaid Program Submissions”). The California Medicaid Program Submissions thereby each constitute a false claim pursuant to Cal. Gov’t Code §12651(a)(1).

82. AstraZeneca knew that the information it supplied to CMS and the California Medicaid Program, including the California Medicaid Program Submissions, was utilized by the United States and the California Medicaid Program to determine the required amount of rebate owed to the California Medicaid Program for each of its Rebate Drugs. AstraZeneca also knew that by submitting the false information at issue here, it fraudulently reduced and underpaid its rebate obligations, thus resulting in great

financial loss to the United States and to California.

83. In addition, AstraZeneca presented or caused the presentment of false or fraudulent claims each time it charged, or caused to be charged, a qualified 340B entity, funded by or an agency or instrumentality of the state government, an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

84. Because of AstraZeneca's conduct in violation of The California False Claims Act, Cal. Gov't Code § 12650 *et seq.*; as set forth in this Count, the State of California suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to Cal. Gov't Code §12651(a)(1).

COUNT 5

VIOLATIONS OF CALIFORNIA FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE GOVERNMENT

52. This is a civil action by the Plaintiff, California, and the Relator, Ven-A-Care, on behalf of California and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, ("AstraZeneca") under the California False Claims Act.

85. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

86. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in Cal. Gov't Code §12650(b)(2)] made, used and caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the California Medicaid Program, in that AstraZeneca submitted false information to the FDA and, thereafter, to CMS and the California Medicaid Program on a quarterly basis, as set forth herein, regarding the Rebate Drugs, including whether

each drug was a different Nexium product or not. By reporting this false information, as well as any inflated Best Prices for Bundled Drugs, AstraZeneca improperly reduced and underpaid the rebate it owed to the California Medicaid Program each time it submitted rebate information and payments to the California Medicaid Program (“the California Medicaid Program Submissions”). The California Medicaid Program Submissions thereby each constitute a false claim pursuant to Cal. Gov’t Code §12651(a)(2).

87. AstraZeneca knew that the information it supplied to CMS and the California Medicaid Program, including its California Medicaid Program Submissions, was utilized by the United States and the California Medicaid Program to determine the required amount of rebate owed to the California Medicaid Program for each of the Rebate Drugs. AstraZeneca also knew that by submitting the false information at issue here, AstraZeneca fraudulently reduced and underpaid its rebate obligations, thus resulting in great financial loss to the United States and to California.

88. In addition, AstraZeneca made or used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved each time it invoiced, charged or otherwise demanded payment, or caused another to invoice, charge or otherwise demand payment, to cause a qualified 340B entity, funded by or an agency or instrumentality of the state government, to pay an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

89. Because of AstraZeneca’s conduct in violation of Cal. Gov’t Code §12651(a)(2) and (3), as set forth in this Count, the State of California suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to Cal. Gov’t Code §12651(a)(2) and (3).

COUNT 6

VIOLATIONS OF CALIFORNIA FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

90. This is a civil action by the Plaintiff, California, and the Relator, Ven-A-Care, on behalf of California and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, (“AstraZeneca”) under the California False Claims Act.

91. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

92. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in Cal. Gov’t Code §12650(b)(2)] made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government. AstraZeneca knew its obligation under the Medicaid Drug Rebate Program, 42 U.S.C. 1396r-8, to make and use truthful records or statements regarding its covered outpatient drugs. AstraZeneca also knew that the information it periodically submitted to CMS and the California Medicaid Program regarding the Rebate Drugs, including the information at issue in this Complaint, was utilized by the United States and the California State Governments to determine the required amount of rebate that each drug manufacturer had to pay to the State of California’s Medicaid Program for each of the Rebate Drugs, including whether the drug was a different product or not. AstraZeneca has made, used or caused to be made or used, false records or statements regarding its Rebate Drugs in order to conceal, avoid, or decrease an obligation to pay or transmit money or property to the California Medicaid Program. AstraZeneca has caused and continue to cause false statements and records to be made or used to decrease its Medicaid Rebate obligation to pay money or property to the California Medicaid Program by falsely indicating in its periodic rebate submissions that rebates were calculated utilizing all Nexium products when in fact they were not and certain discounted sales of the

individually-wrapped Rebate Drugs were not included in the product calculations of all quarterly AMPs and Best Prices throughout the time period at issue. To the extent AstraZeneca also reported in its periodic rebate submissions a falsely inflated best price for any Bundled Drugs, it also caused false statements and records to be made or used to decrease its Medicaid Rebate obligation to pay money or property to the California Medicaid Program. By engaging in the conduct outlined above, AstraZeneca has caused great financial loss to the State of California AstraZeneca's conduct alleged in this Count violates Cal. Gov't Code §12651(a)(7).

93. In addition, AstraZeneca made or used, or caused to be made or used, a false record or statement to conceal, avoid or reduce an obligation to pay or transmit money to the state government each time it invoiced, charged or otherwise demanded payment, or caused another to invoice, charge or otherwise demand payment, to cause a qualified 340B entity, funded by or an agency or instrumentality of the state government, to pay an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

94. Because of AstraZeneca's conduct in violation of The California False Claims Act, Cal. Gov't Code § 12650 *et seq.*, as set forth in this Count, the State of California suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to Cal. Gov't Code §12651(a).

COUNT 7

VIOLATIONS OF DISTRICT OF COLUMBIA FALSE CLAIMS ACT; PRESENTING OR CAUSING THE PRESENTMENT OF FALSE OR FRAUDULENT CLAIMS FOR PAYMENT OR APPROVAL

95. This is a civil action by the Plaintiff, District of Columbia, and the Relator, Ven-A-Care, on behalf of District of Columbia and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, (“AstraZeneca”) under the District of Columbia False Claims Act.

96. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

97. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in D.C. Code Ann. § 2-308.13(3)(a)] has presented or caused to be presented false or fraudulent claims to the District of Columbia Medicaid Program, in that AstraZeneca submitted false information to the FDA and, thereafter, to CMS and the District of Columbia Medicaid Program on at least a quarterly basis, as set forth herein, regarding its Rebate Drugs, including whether each drug (ie., NDC) was a different Nexium product or not. By reporting this false information, as well as any inflated Best Prices for Bundled Drugs, AstraZeneca improperly reduced its rebate amounts and underpaid the rebate it owed to the District of Columbia Medicaid Program each time it submitted rebate information and payments to the District of Columbia Medicaid Prom (“the District of Columbia Medicaid Program Submissions”). The District of Columbia Medicaid Program Submissions thereby each constitute a false claim pursuant to D.C. Code Ann. § 2-308.14(a)(1).

98. AstraZeneca knew that the information it supplied to CMS and the District of Columbia Medicaid Program, including its District of Columbia Medicaid Program Submissions, was utilized by the United States and the District of Columbia Medicaid Program to determine the required amount of rebate owed to the District of Columbia Medicaid Program for each of its Rebate Drugs. AstraZeneca also knew that by

submitting the false information at issue here, AstraZeneca fraudulently reduced and underpaid its rebate obligations, thus resulting in great financial loss to the United States and to District of Columbia.

99. In addition, AstraZeneca presented or caused the presentment of false or fraudulent claims each time it charged, or caused to be charged, a qualified 340B entity, funded by or an agency or instrumentality of the District government, an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

100. Because of AstraZeneca's conduct in violation of The District of Columbia False Claims Act, D.C. Code Ann. §2-308.03 *et seq.*, as set forth in this Count, the District of Columbia suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to D.C. Code Ann. 2-308.14(a).

COUNT 8

VIOLATIONS OF DISTRICT OF COLUMBIA FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE GOVERNMENT

101. This is a civil action by the Plaintiff, District of Columbia, and the Relator, Ven-A-Care, on behalf of District of Columbia and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, ("AstraZeneca") under the District of Columbia False Claims Act.

102. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

103. From on or about February 20, 2001 and continuing to this time, AstraZeneca

knowingly [as defined in D.C. Code Ann. § 2-308.14(a) (2)] has made, used and caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the District of Columbia Medicaid Program , in that AstraZeneca submitted false information to the FDA and, thereafter, to CMS and the District of Columbia Medicaid Program on a quarterly basis, as set forth herein, regarding its Rebate Drugs, including whether each drug (ie., NDC) was a different Nexium product or not. By reporting this false information, as well as any inflated Best Prices for Bundled Drugs, AstraZeneca improperly reduced and underpaid the rebate it owed to the District of Columbia Medicaid Program each time it submitted rebate information and payments to the District of Columbia Medicaid Prom (“the District of Columbia Medicaid Program Submissions”). The District of Columbia Medicaid Program Submissions thereby each constitute a false claim pursuant to D.C. Code Ann. 2-308.14(a)(2).

104. AstraZeneca knew that the information it supplied to CMS and the District of Columbia Medicaid Program, including its District of Columbia Medicaid Program Submissions, was utilized by the United States and the District of Columbia Medicaid Program to determine the required amount of rebate owed to the District of Columbia Medicaid Program for each of its Rebate Drugs. AstraZeneca also knew that by submitting the false information at issue here, AstraZeneca fraudulently reduced and underpaid its rebate obligations, thus resulting in great financial loss to the United States and to District of Columbia.

105. In addition, made or used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved each time it invoiced, charged or otherwise demanded payment, or caused another to invoice, charge or otherwise demand payment, to cause a qualified 340B entity, funded by or an agency or instrumentality of the District government, to pay an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

106. Because of AstraZeneca’s conduct in violation of The District of Columbia False

Claims Act, D.C. Code Ann. §2-308.03 *et seq.*, as set forth in this Count, the District of Columbia suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to D.C. Code Ann 2-308.14 (a).

COUNT 9

VIOLATIONS OF DISTRICT UOF COLUMBIA FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

107. This is a civil action by the Plaintiff, District of Columbia, and the Relator, Ven-A-Care, on behalf of District of Columbia and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, (“AstraZeneca”) under the District of Columbia False Claims Act.

108. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

109. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly has made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government. AstraZeneca knew its obligation under the Medicaid Drug Rebate Program , 42 U.S.C. 1396r-8, to make and use truthful records or statements regarding its covered outpatient drugs. AstraZeneca knew that the information it periodically submitted to CMS and the District of Columbia Medicaid Program regarding its Rebate Drugs, including the information at issue in this Complaint, was utilized by the United States and the District of Columbia State Governments to determine the required amount of rebate that each drug manufacturer had to pay to the State of District of Columbia's Medicaid Program for each of its Rebate Drugs, including whether the drug was a different product or not. AstraZeneca has made, used or caused to be made or used, false records or statements regarding its Rebate Drugs in order to conceal, avoid, or decrease an obligation to pay or transmit money or

property to the District of Columbia Medicaid Program. AstraZeneca has caused and continues to cause false statements and records to be made or used to decrease its Medicaid Rebate obligation to pay money or property to the District of Columbia Medicaid Program by falsely indicating in its periodic rebate submissions that rebates were calculated utilizing all Nexium products when in fact they were not and certain discounted sales of the individually-wrapped Rebate Drugs were not included in the product calculations of all quarterly AMPs and Best Prices throughout the time period at issue. To the extent AstraZeneca also reported in its periodic rebate submissions a falsely inflated Best Price for any Bundled Drugs, it also caused false statements and records to be made or used to decrease its Medicaid Rebate obligation to pay money or property to the District of Columbia Medicaid Program. By engaging in the conduct outlined above, AstraZeneca caused great financial loss to the State of District of Columbia. AstraZeneca's conduct alleged in this Count violates D.C. Code Ann. § 2-308.14(a)(7).

110. In addition, AstraZeneca made or used, or caused to be made or used, a false record or statement to conceal, avoid or reduce an obligation to pay or transmit money to the District government each time it invoiced, charged or otherwise demanded payment, or caused another to invoice, charge or otherwise demand payment, to cause a qualified 340B entity, funded by or an agency or instrumentality of the District government, to pay an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

111. Because of AstraZeneca's conduct in violation of The District of Columbia False Claims Act, D.C. Code Ann. §2-308.03 *et seq.*, as set forth in this Count, the District of Columbia suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to D.C. Code Ann. 2-308.14(a).

COUNT 10

**VIOLATIONS OF DELAWARE FALSE CLAIMS ACT; PRESENTING OR
CAUSING THE PRESENTMENT OF FALSE OR FRAUDULENT CLAIMS FOR PAYMENT
OR APPROVAL**

112. This is a civil action by the Plaintiff, Delaware, and the Relator, Ven-A-Care, on behalf of Delaware and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, (“AstraZeneca”) under the Delaware False Claims Act.

113. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

114. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in Del. Code Ann. § 1202(3)] presented or caused to be presented false or fraudulent claims to the Delaware Medicaid Program, in that AstraZeneca submitted false information to the FDA and, thereafter, to CMS and the Delaware Medicaid Program on at least a quarterly basis, as set forth herein, regarding its Rebate Drugs, including whether each drug (ie., NDC) was a different Nexium product or not. By reporting this false information, as well as any inflated Best Prices for Bundled Drugs, AstraZeneca improperly reduced its rebate amounts and underpaid the rebate it owed to the Delaware Medicaid Program each time it submitted rebate information and payments to the Delaware Medicaid Prom (“the Delaware Medicaid Program Submissions”). The Delaware Medicaid Program Submissions thereby each constitute a false claim pursuant to Del. Code Ann. § 1201(a)(1).

115. AstraZeneca knew that the information it supplied to CMS and the Delaware Medicaid Program, including its Delaware Medicaid Program Submissions, was utilized by the United States and the Delaware Medicaid Program to determine the required amount of rebate owed by AstraZeneca to the Delaware Medicaid Program for each of its Rebate Drugs. AstraZeneca also knew that by submitting the false information at issue here, AstraZeneca fraudulently reduced and underpaid its

rebate obligations, thus resulting in great financial loss to the United States and to Delaware.

116. In addition, AstraZeneca presented or caused the presentment of false or fraudulent claims each time it charged, or caused to be charged, a qualified 340B entity, funded by or an agency or instrumentality of the state government, an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

117. Because of AstraZeneca's conduct in violation of The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §1201 *et seq.*, as set forth in this Count, the State of Delaware suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to Del. Code Ann 1201 (a).

COUNT 11

VIOLATIONS OF DELWARE FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE GOVERNMENT

118. This is a civil action by the Plaintiff, Delaware, and the Relator, Ven-A-Care, on behalf of Delaware and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, ("AstraZeneca") under the Delaware False Claims Act.

119. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

120. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in Del. Code Ann. § 1202(3)] has made, used and caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Delaware Medicaid Program , in that AstraZeneca submitted false information to the FDA and, thereafter, to CMS and the Delaware Medicaid

Program on a quarterly basis, as set forth herein, regarding its Rebate Drugs, including whether each drug (ie., NDC) was a different Nexium product or not. By reporting this false information, as well as any inflated Best Prices for Bundled Drugs, AstraZeneca improperly reduced and underpaid the rebate it owed to the Delaware Medicaid Program each time it submitted rebate information and payments to the Delaware Medicaid Program (“the Delaware Medicaid Program Submissions”). The Delaware Medicaid Program Submissions thereby each constitute a false claim pursuant to Del. Code. Ann. § 1201 (a)(2).

121. AstraZeneca knew that the information it supplied to CMS and the Delaware Medicaid Program, including its Delaware Medicaid Program Submissions, was utilized by the United States and the Delaware Medicaid Program to determine the required amount of rebate owed to the Delaware Medicaid Program for each of its Rebate Drugs. AstraZeneca also knew that by submitting the false information at issue here, AstraZeneca fraudulently reduced and underpaid its rebate obligations, thus resulting in great financial loss to the United States and to Delaware.

122. In addition, AstraZeneca made or used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved each time it invoiced, charged or otherwise demanded payment, or caused another to invoice, charge or otherwise demand payment, to cause a qualified 340B entity, funded by or an agency or instrumentality of the state government, to pay an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

123. Because of AstraZeneca’s conduct in violation of The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §1201 *et seq.*, as set forth in this Count, the State of Delaware suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to Del. Code Ann. § 2-308.14 (a).

COUNT 12

VIOLATIONS OF DELAWARE FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

124. This is a civil action by the Plaintiff, Delaware, and the Relator, Ven-A-Care, on behalf of Delaware and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, (“AstraZeneca”) under the Delaware False Claims Act.

125. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

126. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in Del. Code Ann. § 1202(3)] has made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government. AstraZeneca knew its obligation under the Medicaid Drug Rebate Program, 42 U.S.C. 1396r-8, to make and use truthful records or statements regarding its covered outpatient drugs. AstraZeneca also knew that the information it periodically submitted to CMS and the Delaware Medicaid Program regarding its Rebate Drugs, including the information at issue in this Complaint, was utilized by the United States and the Delaware State Government to determine the required amount of rebate that each drug manufacturer had to pay to the State of Delaware's Medicaid Program for each of its Rebate Drugs, including whether the drug was a different product or not. AstraZeneca has made, used or caused to be made or used, false records or statements regarding its Rebate Drugs in order to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Delaware Medicaid Program. AstraZeneca has caused and continue to cause false statements and records to be made or used to decrease its Medicaid Rebate obligation to pay money or property to the Delaware Medicaid Program by falsely indicating in its periodic rebate submissions

that rebates were calculated utilizing all Nexium products when in fact they were not and certain discounted sales of the individually-wrapped Rebate Drugs were not included in the product calculations of all quarterly AMPs and Best Prices throughout the time period at issue. To the extent AstraZeneca also reported in its periodic rebate submissions a falsely inflated Best Price for any Bundled Drugs, it also caused false statements and records to be made or used to decrease its Medicaid Rebate obligation to pay money or property to the Delaware Medicaid Program. By engaging in the conduct outlined above, AstraZeneca thus has caused great financial loss to the State of Delaware. AstraZeneca's conduct alleged in this Count violate Del. Code Ann. § 1201(7).

127. In addition, AstraZeneca made or used, or caused to be made or used, a false record or statement to conceal, avoid or reduce an obligation to pay or transmit money to the state government each time it invoiced, charged or otherwise demanded payment, or caused another to invoice, charge or otherwise demand payment, to cause a qualified 340B entity, funded by or an agency or instrumentality of the state government, to pay an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

128. Because of AstraZeneca's conduct in violation of The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §1201 *et seq.*, as set forth in this Count, the State of Delaware suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to Del. Code Ann. 1201(a).

COUNT 13

**VIOLATIONS OF FLORIDA FALSE CLAIMS ACT; PRESENTING OR CAUSING
THE PRESENTMENT OF FALSE OR FRAUDULENT CLAIMS FOR PAYMENT OR
APPROVAL**

129. This is a civil action by the Plaintiff, Florida, and the Relator, Ven-A-Care, on behalf of Florida and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, (“AstraZeneca”) under the Florida False Claims Act.

130. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

131. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in Florida False Claims Act § 68.082(1)(c)] has presented or caused to be presented false or fraudulent claims to the Florida Medicaid Program, in that AstraZeneca submitted false information to the FDA and, thereafter, to CMS and the Florida Medicaid Program on at least a quarterly basis, as set forth herein, regarding its Rebate Drugs, including whether each drug (ie., NDC) was a different Nexium product or not. By reporting this false information, as well as any inflated Best Prices for Bundled Drugs, AstraZeneca improperly reduced its rebate amounts and underpaid the rebate it owed to the Florida Medicaid Program each time it submitted rebate information and payments to the Florida Medicaid Program (“the Florida Medicaid Program Submissions”). The Florida Medicaid Program Submissions thereby each constitute a false claim pursuant to Florida False Claims Act § 68.082 (2)(a).

132. AstraZeneca knew that the information it supplied to CMS and the Florida Medicaid Program, including its Florida Medicaid Program Submissions, was utilized by the United States and the Florida Medicaid Program to determine the required amount of rebate owed by AstraZeneca to the Florida Medicaid Program for each of its Rebate Drugs. AstraZeneca also knew that by submitting the false information at issue here, AstraZeneca fraudulently reduced and underpaid its rebate obligations, thus resulting in great

financial loss to the United States and to Florida.

133. In addition, AstraZeneca presented or caused the presentment of false or fraudulent claims each time it charged, or caused to be charged, a qualified 340B entity, funded by or an agency or instrumentality of the state government, an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

134. Because of AstraZeneca's conduct in violation of The Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*, as set forth in this Count, the State of Florida suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to Fla. Stat. § 68.082 (2).

COUNT 14

VIOLATIONS OF FLORIDA FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE GOVERNMENT

135. This is a civil action by the Plaintiff, Florida, and the Relator, Ven-A-Care, on behalf of Florida and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, ("AstraZeneca") under the Florida False Claims Act.

136. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

137. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in Florida False Claims Act § 68.082(1)(c)] has made, used and caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Florida Medicaid Program, in that AstraZeneca submitted false information to the FDA and, thereafter, to CMS and the

Florida Medicaid Program on a quarterly basis, as set forth herein, regarding its Rebate Drugs, including whether each drug (ie., NDC) was a different Nexium product or not. By reporting this false information, as well as any inflated Best Prices for Bundled Drugs, AstraZeneca improperly reduced and underpaid the rebate it owed to the Florida Medicaid Program each time it submitted rebate information and payments to the Florida Medicaid Program (“the Florida Medicaid Program Submissions”). The Florida Medicaid Program Submissions thereby each constitute a false claim pursuant to Fla. Stat. § 68.082 (2)(b).

138. AstraZeneca knew that the information it supplied to CMS and the Florida Medicaid Program, including its Florida Medicaid Program Submissions, was utilized by the United States and the Florida Medicaid Program to determine the required amount of rebate owed to the Florida Medicaid Program for each of its Rebate Drugs. AstraZeneca also knew that by submitting the false information at issue here, AstraZeneca fraudulently reduced and underpaid its rebate obligations, thus resulting in great financial loss to the United States and to Florida.

139. In addition, made or used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved each time it invoiced, charged or otherwise demanded payment, or caused another to invoice, charge or otherwise demand payment, to cause a qualified 340B entity, funded by or an agency or instrumentality of the state government, to pay an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

140. Because of AstraZeneca’s conduct in violation of The Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*, as set forth in this Count, the State of Florida suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to Fla. Stat. § 68.082(2).

COUNT 15

VIOLATIONS OF FLORIDA FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

141. This is a civil action by the Plaintiff, Florida, and the Relator, Ven-A-Care, on behalf of Florida and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, (“AstraZeneca”) under the Florida False Claims Act.

142. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

143. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined Florida False Claims Act § 68.082(1)(c)] has made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government. AstraZeneca knew its obligation under the Medicaid Drug Rebate Program, 42 U.S.C. 1396r-8, to make and use truthful records or statements regarding its covered outpatient drugs. AstraZeneca also knew that the information it periodically submitted to CMS and the Florida Medicaid Program regarding its Rebate Drugs, including the information at issue in this Complaint, was utilized by the United States and the Florida State Government to determine the required amount of rebate that each drug manufacturer had to pay to the State of Florida's Medicaid Program for each of its Rebate Drugs, including whether the drug (ie., NDC) was a different product or not. AstraZeneca has made, used or caused to be made or used, false records or statements regarding its Rebate Drugs in order to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Florida Medicaid Program. AstraZeneca has caused and continue to cause false statements and records to be made or used to decrease its Medicaid Rebate obligation to pay money or property to the Florida Medicaid Program by falsely indicating in its periodic rebate submissions that rebates were calculated utilizing all Nexium products when in fact they were not and certain discounted sales of the

individually-wrapped Rebate Drugs were not included in the product calculations of all quarterly AMPs and Best Prices throughout the time period at issue. To the extent AstraZeneca also reported in its periodic rebate submissions a falsely inflated best price for any Bundled Drugs, it also caused false statements and records to be made or used to decrease its Medicaid Rebate obligation to pay money or property to the Florida Medicaid Program. By engaging in the conduct outlined above, AstraZeneca thus has caused great financial loss to the State of Florida. AstraZeneca ' conduct as alleged in this Count violates Florida False Claims Act § 68.802(2)(g).

144. In addition, AstraZeneca made or used, or caused to be made or used, a false record or statement to conceal, avoid or reduce an obligation to pay or transmit money to the state government each time it invoiced, charged or otherwise demanded payment, or caused another to invoice, charge or otherwise demand payment, to cause a qualified 340B entity, funded by or an agency or instrumentality of the state government, to pay an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

145. Because of AstraZeneca's conduct in violation of The Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*, as set forth in this Count, the State of Florida suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to Fla. Stat. 68.082(2).

COUNT 16

**VIOLATIONS OF GEORGIA FALSE CLAIMS ACT; PRESENTING OR CAUSING
THE PRESENTMENT OF FALSE OR FRAUDULENT CLAIMS FOR PAYMENT OR
APPROVAL**

146. This is a civil action by the Plaintiff, Georgia, and the Relator, Ven-A-Care, on behalf of Georgia and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, (“AstraZeneca”) under the Georgia False Claims Act.

147. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

148. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in Official Code of Georgia Ann. § 49-4-168(2)] has presented or caused to be presented false or fraudulent claims to the Georgia Medicaid Program, in that AstraZeneca submitted false information to the FDA and, thereafter, to CMS and the Georgia Medicaid Program on at least a quarterly basis, as set forth herein, regarding its Rebate Drugs, including whether each drug (ie., NDC) was a different Nexium product or not. By reporting this false information, as well as any inflated Best Prices for Bundled Drugs, AstraZeneca improperly reduced its rebate amounts and underpaid the rebate it owed to the Georgia Medicaid Program each time it submitted rebate information and payments to the Georgia Medicaid Prom (“the Georgia Medicaid Program Submissions”). The Georgia Medicaid Program Submissions thereby each constitute a false claim pursuant to Official Code of Georgia Ann. § 49-4-168.1(a)(1).

149. AstraZeneca knew that the information it supplied to CMS and the Georgia Medicaid Program, including its Georgia Medicaid Program Submissions, was utilized by the United States and the Georgia Medicaid Program to determine the required amount of rebate owed by them to the Georgia Medicaid Program for each of its Rebate Drugs. AstraZeneca also knew that by submitting the false information at issue here, AstraZeneca fraudulently reduced and underpaid its rebate obligations, thus resulting in great

financial loss to the United States and to Georgia.

150. In addition, AstraZeneca presented or caused the presentment of false or fraudulent claims each time it charged, or caused to be charged, a qualified 340B entity, funded by or an agency or instrumentality of the state government, an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

151. Because of AstraZeneca's conduct in violation of The Georgia False Claims Act, Official Code of Georgia Ann. § 49-4-168 *et seq.*, as set forth in this Count, the State of Georgia suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to Official Code of Georgia Ann. § 49-4-168.1(a) .

COUNT 17

VIOLATIONS OF GEORGIA FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE GOVERNMENT

152. This is a civil action by the Plaintiff, Georgia, and the Relator, Ven-A-Care, on behalf of Georgia and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, ("AstraZeneca") under the Georgia False Claims Act.

153. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

154. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in Official Code of Georgia Ann. § 49-4-168(2)] has made, used and caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Georgia Medicaid Program , in that AstraZeneca submitted false information to the FDA and, thereafter, to CMS and the

Georgia Medicaid Program on a quarterly basis, as set forth herein, regarding its Rebate Drugs, including whether each drug (ie., NDC) was a different Nexium product or not. By reporting this false information, as well as any inflated Best Prices for Bundled Drugs, AstraZeneca improperly reduced and underpaid the rebate it owed to the Georgia Medicaid Program each time it submitted rebate information and payments to the Georgia Medicaid Program (“the Georgia Medicaid Program Submissions”). The Georgia Medicaid Program Submissions thereby each constitute a false claim pursuant to the Official Code of Georgia Ann. § 49-4-168.1(a)(2).

155. AstraZeneca knew that the information it supplied to CMS and the Georgia Medicaid Program, including its Georgia Medicaid Program Submissions, was utilized by the United States and the Georgia Medicaid Program to determine the required amount of rebate owed to the Georgia Medicaid Program for each of its Rebate Drugs. AstraZeneca also knew that by submitting the false information at issue here, AstraZeneca fraudulently reduced and underpaid its rebate obligations, thus resulting in great financial loss to the United States and to Georgia.

156. In addition, AstraZeneca made or used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved each time it invoiced, charged or otherwise demanded payment, or caused another to invoice, charge or otherwise demand payment, to cause a qualified 340B entity, funded by or an agency or instrumentality of the state government, to pay an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

157. Because of AstraZeneca’s conduct in violation of The Georgia False Claims Act, Official Code of Georgia Ann. § 49-4-168 *et seq.*, as set forth in this Count, the State of Georgia suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to the Official Code of Georgia

Ann. § 49-4-168.1(a).

COUNT 18

**VIOLATIONS OF GEORGIA FALSE CLAIMS ACT; MAKING, USING, OR
CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL,
AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR
PROPERTY TO THE GOVERNMENT**

158. This is a civil action by the Plaintiff, Georgia, and the Relator, Ven-A-Care, on behalf of Georgia and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, (“AstraZeneca”) under the Georgia False Claims Act.

159. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

160. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in the Official Code of Georgia Ann. § 49-4-168(2)] has made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government. AstraZeneca knew its obligation under the Medicaid Drug Rebate Program, 42 U.S.C. 1396r-8, to make and use truthful records or statements regarding its covered outpatient drugs. AstraZeneca also knew that the information it periodically submitted to CMS and the Georgia Medicaid Program regarding its Rebate Drugs, including the information at issue in this Complaint, was utilized by the United States and the Georgia State Government to determine the required amount of rebate that each drug manufacturer had to pay to the State of Georgia's Medicaid Program for each of its Rebate Drugs, including whether the drug (ie., NDC) was a different product or not. AstraZeneca has made, used or caused to be made or used, false records or statements regarding its Rebate Drugs in order to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Georgia Medicaid Program. AstraZeneca has caused and continues to cause false statements and records to be made or used to decrease its Medicaid Rebate obligation to pay money or property to the Georgia Medicaid Program by falsely indicating in its periodic rebate

submissions that rebates were calculated utilizing all Nexium products when in fact they were not and certain discounted sales of the individually-wrapped Rebate Drugs were not included in the product calculations of all quarterly AMPs and Best Prices throughout the time period at issue. To the extent AstraZeneca also reported in its periodic rebate submissions a falsely inflated Best Price for any Bundled Drugs, it also caused false statements and records to be made or used to decrease its Medicaid Rebate obligation to pay money or property to the Georgia Medicaid Program. By engaging in the conduct outlined above, AstraZeneca thus has caused great financial loss to the State of Georgia. AstraZeneca's conduct set forth in this Count violated Official Code of Georgia Ann. § 49-4-168.1(a)(7).

161. In addition, AstraZeneca made or used, or caused to be made or used, a false record or statement to conceal, avoid or reduce an obligation to pay or transmit money to the state government each time it invoiced, charged or otherwise demanded payment, or caused another to invoice, charge or otherwise demand payment, to cause a qualified 340B entity, funded by or an agency or instrumentality of the state government, to pay an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

162. Because of AstraZeneca's conduct in violation of The Georgia False Claims Act, Official Code of Georgia Ann. § 49-4-168 *et seq.*, as set forth in this Count, the State of Georgia suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to Official Code of Georgia Ann. § 49-4-168.1(a)

COUNT 19

VIOLATIONS OF HAWAII FALSE CLAIMS ACT; PRESENTING OR CAUSING THE PRESENTMENT OF FALSE OR FRAUDULENT CLAIMS FOR PAYMENT OR APPROVAL

163. This is a civil action by the Plaintiff, Hawaii, and the Relator, Ven-A-Care, on behalf

of Hawaii and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, (“AstraZeneca”) under the Hawaii False Claims Act.

164. Relator realleges and incorporates by reference paragraphs 1 through 65 as if fully set forth herein and further alleges as follows:

165. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in Haw. Rev. Stat. § 661-21(e)] has presented or caused to be presented false or fraudulent claims to the Hawaii Medicaid Program, in that AstraZeneca submitted false information to the FDA and, thereafter, to CMS and the Hawaii Medicaid Program on at least a quarterly basis, as set forth herein, regarding its Rebate Drugs, including whether each drug was a different Nexium product or not. By reporting this false information, as well as any inflated Best Prices for Bundled Drugs, AstraZeneca improperly reduced its rebate amounts and underpaid the rebate it owed to the Hawaii Medicaid Program each time it submitted rebate information and payments to the Hawaii Medicaid Prom (“the Hawaii Medicaid Program Submissions”). The Hawaii Medicaid Program Submissions thereby each constitute a false claim pursuant to Haw. Rev. Stat. § 661-21(a)(1).

166. AstraZeneca knew that the information it supplied to CMS and the Hawaii Medicaid Program, including its Hawaii Medicaid Program Submissions, was utilized by the United States and the Medicaid Program to determine the required amount of rebate owed to the Hawaii Medicaid Program for each of its Rebate Drugs. AstraZeneca also knew that by submitting the false information at issue here, AstraZeneca fraudulently reduced and underpaid its rebate obligations, thus resulting in great financial loss to the United States and to Hawaii.

167. In addition, AstraZeneca presented or caused the presentment of false or fraudulent claims each time it charged, or caused to be charged, a qualified 340B entity, funded by or an agency or instrumentality of the state government, an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

168. Because of AstraZeneca's conduct in violation of The Hawaii False Claims Act, Haw. Rev. Stat. §661-21 *et seq.*, as set forth in this Count, the State of Hawaii suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to Haw. Rev. Stat. § 661-21(a).

COUNT 20

VIOLATIONS OF HAWAII FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE GOVERNMENT

169. This is a civil action by the Plaintiff, Hawaii, and the Relator, Ven-A-Care, on behalf of Hawaii and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, ("AstraZeneca") under the Hawaii False Claims Act.

170. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

171. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in Haw. Rev. Stat. § 661-21(e)] has made, used and caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Hawaii Medicaid Program, in that AstraZeneca submitted false information to the FDA and, thereafter, to CMS and the Hawaii Medicaid Program on a quarterly basis, as set forth herein, regarding its Rebate Drugs, including whether each drug was a different Nexium product or not. By reporting this false information, as well as any inflated Best Prices for Bundled Drugs, AstraZeneca improperly reduced and underpaid the rebate it owed to the Hawaii Medicaid Program each time it submitted rebate information and payments to the Hawaii Medicaid Program ("the Hawaii Medicaid Program Submissions"). The Hawaii Medicaid Program Submissions thereby each constitute a

false claim pursuant to Haw. Rev. Stat. § 661-21(a)(2).

172. AstraZeneca knew that the information it supplied to CMS and the Hawaii Medicaid Program, including its Hawaii Medicaid Program Submissions, was utilized by the United States and the Hawaii Medicaid Program to determine the required amount of rebate owed to the Hawaii Medicaid Program for each of its Rebate Drugs. AstraZeneca also knew that by submitting the false information at issue here, AstraZeneca fraudulently reduced and underpaid its rebate obligations, thus resulting in great financial loss to the United States and to Hawaii.

173. In addition, AstraZeneca made or used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved each time it invoiced, charged or otherwise demanded payment, or caused another to invoice, charge or otherwise demand payment, to cause a qualified 340B entity, funded by or an agency or instrumentality of the state government, to pay an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

174. Because of AstraZeneca's conduct in violation of The Hawaii False Claims Act, Haw. Rev. Stat. §661-21 *et seq.*, as set forth in this Count, the State of Hawaii suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to Haw. Rev. Stat. § 661-21(a)(2).

COUNT 21

VIOLATIONS OF HAWAII FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

175. This is a civil action by the Plaintiff, Hawaii, and the Relator, Ven-A-Care, on behalf of Hawaii and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and

AstraZeneca PLC, (“AstraZeneca”) under the Hawaii False Claims Act.

176. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

177. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined Haw. Rev. Stat. § 661-21(e)] has made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government. AstraZeneca knew its obligation under the Medicaid Drug Rebate Program, 42 U.S.C. 1396r-8, to make and use truthful records or statements regarding its covered outpatient drugs. AstraZeneca also knew that the information it periodically submitted to CMS and the Hawaii Medicaid Program regarding its Rebate Drugs, including the information at issue in this Complaint, was utilized by the United States and the Hawaii State Governments to determine the required amount of rebate that each drug manufacturer had to pay to the State of Hawaii’s Medicaid Program for each of its Rebate Drugs, including whether the drug was a different product or not. AstraZeneca has made, used or caused to be made or used, false records or statements regarding its Rebate Drugs in order to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Hawaii Medicaid Program. AstraZeneca has caused and continue to cause false statements and records to be made or used to decrease its Medicaid Rebate obligation to pay money or property to the Hawaii Medicaid Program by falsely indicating in its periodic rebate submissions that rebates were calculated utilizing all Nexium products when in fact they were not and certain discounted sales of the individually-wrapped Rebate Drugs were not included in the product calculations of all quarterly AMPs and Best Prices throughout the time period at issue. To the extent AstraZeneca also reported in its periodic rebate submissions a falsely inflated best price for any Bundled Drugs, it also caused false statements and records to be made or used to decrease its Medicaid Rebate obligation to pay money or property to the Hawaii Medicaid Program. By engaging in the conduct outlined above, AstraZeneca thus has caused great financial loss to the State of Hawaii. AstraZeneca’s conduct alleged in this Count violates Haw. Rev. Stat. § 661-21(a)(7).

178. In addition, AstraZeneca made or used, or caused to be made or used, a false record or

statement to conceal, avoid or reduce an obligation to pay or transmit money to the state government each time it invoiced, charged or otherwise demanded payment, or caused another to invoice, charge or otherwise demand payment, to cause a qualified 340B entity, funded by or an agency or instrumentality of the state government, to pay an amount in excess of the 340B Ceiling Price and failed to make or arrange a refund sufficient to reduce the total charge to the 340B Ceiling Price.

179. Because of AstraZeneca's conduct in violation of The Hawaii False Claims Act, Haw. Rev. Stat. §661-21 *et seq.*, as set forth in this Count, the State of Hawaii suffered actual damages and is entitled to damages, multiple damages and penalties in excess of Four Hundred Thousand Dollars (\$400,000) pursuant to Haw. Rev. Stat. § 661-21(a).

COUNT 22

**VIOLATIONS OF ILLINOIS FALSE CLAIMS ACT; PRESENTING OR CAUSING
THE PRESENTMENT OF FALSE OR FRAUDULENT CLAIMS FOR PAYMENT OR
APPROVAL**

180. This is a civil action by the Plaintiff, Illinois, and the Relator, Ven-A-Care, on behalf of Illinois and on behalf of the Relator, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra Pharmaceuticals LP, AstraZeneca USA, Inc., Astra USA, Inc and AstraZeneca PLC, (“AstraZeneca”) under the Illinois False Claims Act.

181. Relator realleges and incorporates by reference paragraphs 1 through 64 as if fully set forth herein and further alleges as follows:

182. From on or about February 20, 2001 and continuing to this time, AstraZeneca knowingly [as defined in 740 Ill. Code Stat. 175 § 3(b)] has presented or caused to be presented false or fraudulent claims to the Illinois Medicaid Program, in that AstraZeneca submitted false information to the FDA and, thereafter, to CMS and the Illinois Medicaid Program on at least a quarterly basis, as set forth herein, regarding its Rebate Drugs, including whether each drug was a different Nexium product or not. By reporting this false information, as well as any inflated Best Prices for Bundled Drugs, AstraZeneca improperly reduced its rebate amounts and underpaid the rebate it owed to the Illinois Medicaid Program each time it submitted rebate information and payments to the Illinois Medicaid Program (“the Illinois Medicaid Program Submissions”). The Illinois Medicaid Program Submissions thereby each constitute a false claim pursuant to Illinois Whistleblower Reward and Protection Act, 740 Ill. Code Stat. 175 § 3(a) (1).

183. AstraZeneca knew that the information it supplied to CMS and the Illinois Medicaid Program, including its Illinois Medicaid Program Submissions, was utilized by the United States and the Illinois Medicaid Program to determine the required amount of rebate owed to the Illinois Medicaid Program for each of its Rebate Drugs. AstraZeneca also knew that by submitting the false information at issue here, AstraZeneca fraudulently reduced and underpaid its rebate obligations, thus resulting in great